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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/851,372	05/07/2001	Michael R. Forman	20534-000500	2385

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EXAMINER

WILLIAMS, CATHERINE SERKE

ART UNIT PAPER NUMBER

3763

DATE MAILED: 05/19/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/851,372	FORMAN, MICHAEL R.	
	Examiner	Art Unit	
	Catherine S. Williams	3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 April 2004.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) 3, 4 and 18 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 2, 5-17 and 21 is/are rejected.
- 7) ☒ Claim(s) 19-20 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

The Request for Continued Examination and Amendment dated 02/27/2004 have been entered into the file.

Information Disclosure Statement

Presently, the application does not contain a 1449 with a filing date on or near 09/05/2001. This application contains three 1449(s) with filing dates of 04/15/2002; 10/28/2002 and 10/07/2002. If the 09/05/2001 1449 was previously submitted, it is suggested that applicant fax a copy with the return filing card from the USPTO so the 1449 may be entered into the file. If applicant needs copies of the three 1449s listed above, please reference which one(s) to include in the next correspondence.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-2,5,8-17 and 21 are rejected under 35 U.S.C. 102(b) as being anticipated by Winkler et al (US Pat# 6,200,257).

Winkler discloses a catheter body having a proximal end and a distal end (see figures 1B and 3). An ionizing radiation source (32), including x-ray, is coupleable to the catheter body

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within a balloon for applying a radiation dose to a body lumen. Means including infusion holes, hydrogel (matrix) coated balloons, or a microporous balloon are coupleable to the catheter body for releasing a therapeutic agent. See 4:30-34; 9:33+; 10:49+. The therapeutic agent is a radiosensitizer. The radiation and drug delivery catheter is used to inhibit hyperplasia (see 6:65). It is considered inherent that the hydrogel coating is a rate controlling material that releases the agent through diffusion, degradation of the matrix and from pores in the material. The radiosensitizer includes taxol, misonidazol and texaphyrin. See 5:10,48 and 6:14.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Winkler in view of Regulla et al(US Pat# 6,001,054).

Winkler meets the claim limitations as described above but fails to disclose taxol being attached or encapsulated in a lipid or surfactant carrier.

However, Regulla discloses a method and apparatus for energy application for local dose enhancement of ionizing radiation that includes the administration of taxol within a lipid carrier. The administration with the liposome is for a more prolonged local action.

At the time of the invention, it would have been obvious to incorporate the administration of taxol within a lipid carrier into the invention of Winkler. The devices are analogous in the art

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and used to treat tissue that is proliferating. The motivation for the incorporation would have been in order to enhance the application of the invention of Winkler by providing a prolonged result as taught by Regulla.

Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Winkler in view of Regulla.

Winkler in view of Regulla meet the claim limitations as described above but fail to include incorporating taxol into a solution with polyoxyethylated castor oil and dehydrated alcohol.

At the time of the invention, it would have been obvious to incorporate taxol into a solution with polyoxyethylated castor oil and dehydrated alcohol. Regulla teaches the use of taxol with liposomes and a solution with polyoxyethylated castor oil and dehydrated alcohol is an equivalent in the art. The motivation for the substitution would have been an obvious design choice. The disclosure of the instant application has asserted no advantage, particular purpose or solution to a problem for the inclusion of incorporating taxol into a solution with polyoxyethylated castor oil and dehydrated alcohol versus liposomes. Therefore the motivation for the substitution would have been to utilize readily available materials for ease of production.

Allowable Subject Matter

Claims 19-20 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

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Response to Arguments

Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. US Pat 5,945,439 discloses a similar method to the instant invention.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Catherine S. Williams whose telephone number is 703-308-4846. The examiner can normally be reached on Monday - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on 703-308-3552. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Catherine S. Williams *Csw.*
May 16, 2004


LOAN H. THANH
PRIMARY EXAMINER